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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/702,316	11/05/2003	Norman Milstein	M 6212C-NHG/ST	7930
23657	7590	11/22/2006	EXAMINER	
COGNIS CORPORATION PATENT DEPARTMENT 300 BROOKSIDE AVENUE AMBLER, PA 19002			HANDY, NIKKI R	
			ART UNIT	PAPER NUMBER
			1616	

DATE MAILED: 11/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/702,316

Applicant(s)

MILSTEIN ET AL.

Examiner

Nikki Handy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 93-110 is/are pending in the application.
- 4a) Of the above claim(s) 110 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 93-109 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 93-109, are drawn to a food additive composition comprising: a) an edible solubilizing agent, b) an effective amount of a suitable dispersant, c) an effective amount of an antioxidant, and d) an ester, classified in class 424, subclass 439.
- II. Claim 110, is drawn to a method of reducing the absorption of cholesterol comprising administering the food additive comprising: a) an edible solubilizing agent, b) an effective amount of a suitable dispersant, c) an effective amount of an antioxidant, and d) an ester, to a mammal, classified in class 424, subclass 439.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the process for using the product as claimed can be practiced with another materially different product, such as, using natural waxes or wax sub-fractions to maintain healthy blood lipid profiles by lowering total cholesterol, lowering LDL-cholesterol, raising HDL cholesterol, and/or

lowering triglyceride levels as evidenced by Hargrove et al. (US Patent Application No. US 2006/0127449 A1, page 1, paragraph 1).

Notice of Possible Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double

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patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

During a telephone conversation with Attorney Jack Daniels on October 24, 2006 a provisional election was made with traverse to prosecute the invention of Group I, claims 93-109. Affirmation of this election must be made by applicant in replying to this Office action. Claim 110 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 93-109 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 7, 8, 11, 12, and 13-18 of U.S. Patent No. 6,394,230 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because both application and USPN '230 claim a food additive composition that is useful for lowering cholesterol. The scope of the application claims differs from the USPN '230 claims in that the USPN '230 makes claim to a food additive comprising a reaction mixture formed by reacting at least one member selected from the group consisting of sterols, stanols, and combinations thereof with at least one member selected from the group consisting of carboxylic acids and carboxylic acid esters in the presence of a catalytically effective amount of a catalyst selected from the group consisting of calcium oxide, calcium hydroxide, a calcium salt of a carboxylic acid, magnesium hydroxide and combinations thereof, wherein said reaction mixture includes at least a portion of said catalyst, whereas, the instant application claims a food additive composition comprising: (a) an edible solubilizing agent; (b) an effective

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amount of a suitable disperant; (c) an effective amount of an antioxidant; and (d) an ester prepared by reacting at least one first reactant selected from the group consisting of sterols, stanols, and combinations thereof with at least one second reactant selected from the group consisting of carboxylic acids and carboxylic acid esters in the presence of a catalytically effective amount of a catalyst selected from the group consisting of calcium oxide, calcium hydroxide, a calcium salt of a carboxylic acid, magnesium hydroxide and combinations thereof. USPN '230 recites the following: a food additive **comprising** a reaction mixture, etc. The terminology, comprising, is a term which allows for the inclusion of unrecited components. The additional unrecited components in the instant claims are an edible solubilizing agent, an effective amount of a suitable dispersant, and an effective amount of an antioxidant. It would be obvious to one of ordinary skill in the art to include the additional ingredients because the USPN '230 makes claim to the food additive comprising a reaction mixture by reacting at least one member selected from the group consisting of sterols, stanols and combinations thereof with at least one member selected from the group consisting of carboxylic acids and carboxylic acid esters in the presence of a catalytically effective amount of a catalyst alone. The USPN '230 inherently claims the invention of the instant application where the food additive composition is employed with an edible solubilizing agent, an effective amount of a suitable dispersant, and an effective amount of an antioxidant.

Telephone Inquiry

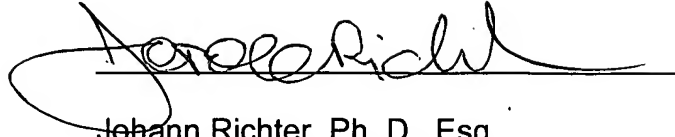
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nikki Handy whose telephone number is (571) 272-9923. The examiner can normally be reached on Monday-Friday 8:30 am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Nikki Handy
Patent Examiner
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A handwritten signature in black ink, appearing to read "Johann Richter", is written over a horizontal line. The signature is fluid and cursive.

Johann Richter, Ph. D., Esq.
Supervisory Patent Examiner
Technology Center 1600